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| 10/570,123 | 03/19/2007 | Stephen Noel Fitzgerald | C&R-114 | 7426 |

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| EXAMINER | |
|---|---|
| HUYNH, PHUONG N | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1644 | |

| NOTIFICATION DATE | DELIVERY MODE |
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| 02/03/2010 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

euspto@slspatents.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/570,123 | FITZGERALD ET AL. | |
| | Examiner | Art Unit | |
| | PHUONG HUYNH | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *One* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *2/28/06*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *49-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *49-70* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**DETAILED ACTION**

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 52-71 been renumbered 51-70.

Claims 49-70 are pending.

The following informality is noted.

- Claim 49 encompasses multiple distinct products such as polypeptide of any one of a1) through 15), polynucleotide of any one of b1) to d), ligand or antibody (e), compound that increases the level of expression or activity of a polypeptide (f1), compound that decreases the level of expression or activity of a polypeptide (f2), a compound that is a ligand that binds to a polypeptide according to any a1) to a15), a compound that is an enzyme that binds to a polypeptide according to any a1) to a15), a compound that is a receptor that that binds to a polypeptide according to any a1) to a15), a compound that is structural or functional mimetic to a polypeptide according to any a1) to a15), and transgenic or knockout non-human animal.

  Products such as polypeptides, polynucleotides, antibody, compound that increases the level of expression or activity of a polypeptide (f1), compound that decreases the level of expression or activity of a polypeptide (f2), a compound that is a ligand that binds to a polypeptide according to any a1) to a15), a compound that is an enzyme that binds to a polypeptide according to any a1) to a15), a compound that is a receptor that that binds to a polypeptide according to any a1) to a15), a compound that is structural or functional mimetic to a polypeptide according to any a1) to a15), and transgenic or knockout non-human animal differ with respect to their structure, function and effects. A person of ordinary skill in the art would not envision one in view of the other. Therefore, the restriction has been set forth for each as separate Group of Invention, irrespective of the format of the claims.

- Use claim 50 fails to conform to the US practice. Further, claim 50 encompasses multiples methods such as method of diagnosing a specific diseases, method of treating a specific disease, method of monitoring the therapeutic treatment of a specific disease, method of identifying compound or screening candidate compound using distinct products such as polypeptide (a1 through a15), polynucleotide (b1-5 through d), ligand or antibody (e), compound that *increases* the level of expression or activity of a polypeptide (f1), compound that *decreases* the level of expression or activity of a polypeptide (f2), a compound that is a ligand that binds to a polypeptide according to any a1) to a15), a compound that is an enzyme that binds to a polypeptide according to any a1) to a15), a compound that is a receptor that that binds to a polypeptide according to any a1) to a15), a compound that is structural or functional mimetic to a polypeptide according to any a1) to a15).

  "The method of use" in claim 50 has been interpreted as method of diagnosing a specific diseases, method of treating a specific disease, method of monitoring the therapeutic treatment of a specific disease, method of identifying compound or screening candidate compound using distinct products such as polypeptide (a1 through a15), polynucleotide (b1-5 through d), ligand or antibody (e), compound that increases the level of expression or activity of a polypeptide (f1), compound that decreases the level of expression or activity of a polypeptide (f2), a compound that is a ligand that binds to a polypeptide according to any a1) to a15), a compound that is an enzyme that binds to a polypeptide according to any a1) to a15), a compound that is a receptor that that binds to a polypeptide according to any a1) to a15), a compound that is structural or functional mimetic to a polypeptide according to any a1) to a15), irrespective of the format of the claim.

## REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

**When Claims Are Directed to Multiple Categories of Inventions:**

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1)A product and a process specially adapted for the manufacture of said product; or

(2)A product and process of use of said product; or

(3)A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4)A process and an apparatus or means specifically designed for carrying out the said process; or

(5)A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

**Restriction is required under 35 U.S.C. 121 and 372.**

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 49 and 69-70, drawn to a composition of matter comprising an isolated **polypeptide** as set forth in a1) through 15), a vaccine comprising said polypeptide as set forth in j), a structural or functional mimetic thereof, a pharmaceutical composition comprising said polypeptide and a pharmaceutically acceptable carrier as set forth in i).

II. Claim 49, drawn to a composition of matter comprising a purified **polynucleotide** as set forth in b1) to b5), vector and host cell comprising said polynucleotide, a vaccine comprising said polynucleotide as set froth in j), a kit comprising nucleic acid probe as set forth in k) through m) and a pharmaceutical composition comprising said polynucleotide and a pharmaceutically acceptable carrier as set forth in i).

III. Claim 49, drawn to a composition of matter comprising an **antibody** that binds to the **polypeptide** as set forth in e1) to e2), a kit comprising said antibody as set forth in n), a compound that is a ligand that binds to a polypeptide according to any a1) to a15) without inducing any biological effect of

any polypeptide and a pharmaceutical composition comprising said antibody and a pharmaceutically acceptable carrier as set forth in i).

IV. Claim 49, drawn to a composition of matter comprising a **compound** that binds *increases* the level of expression of a polypeptide as set forth in f1) and a pharmaceutical composition comprising said compound and a pharmaceutically acceptable carrier as set forth in i).

V. Claim 49, drawn to a composition of matter comprising a **compound** that binds *decreases* the level of expression of a polypeptide as set forth in f2) and a pharmaceutical composition comprising said compound and a pharmaceutically acceptable carrier as set forth in i).

VI. Claim 49, drawn to a composition of matter comprising a **compound** that binds *increases* the activity of a polypeptide as set forth in f1) and a pharmaceutical composition comprising said compound and a pharmaceutically acceptable carrier as set forth in i).

VII. Claim 49, drawn to a composition of matter comprising a **compound** that binds *decreases* the activity of a polypeptide as set forth in f2) and a pharmaceutical composition comprising said compound and a pharmaceutically acceptable carrier as set forth in i).

VIII. Claim 49, drawn to a composition of matter comprising a compound that is an **enzyme** that binds to a polypeptide according to any a1) to a15) as set forth in h) and a pharmaceutical composition comprising said enzyme and a pharmaceutically acceptable carrier as set forth in i).

IX. Claim 49, drawn to a composition of matter comprising a compound that is a **receptor** that binds to a polypeptide according to any a1) to a15) as set forth in h) and a pharmaceutical composition comprising said receptor and a pharmaceutically acceptable carrier as set forth in i).

X. Claim 49, drawn to a **transgenic non-human animal** that has been transformed to express higher levels of a polypeptide as set forth in any one of a1) to a15).

XI. Claim 49, drawn to a **knockout non-human animal** that has been transformed to express lower or absent levels of a polypeptide as set forth in any one of a1) to a15).

XII. Claims 51-53 and 63-64, drawn to a **method of treating a specific disease** using a specific composition comprising administering to the patient a composition comprising an isolated **polypeptide** as set froth in a) to 15) or structural or functional mimetic thereof.

XIII. Claims 51-53 and 63-64, drawn to a **method of treating a specific disease** using a specific composition comprising administering to the patient a composition comprising a purified **polynucleotide**, vector or host cell comprising said polynucleotide as set forth in b1) through d).

XIV. Claims 51-53, drawn to a **method of treating a specific disease** using a specific composition comprising administering to the patient a composition comprising a ligand or **antibody** that binds specifically to the polypeptide of any of a1) to a15).

XV. Claims 51-53, drawn to a **method of treating a specific disease** using a specific composition comprising administering to the patient a composition comprising a **compound** that ***increases*** **the level of expression** of a polypeptide as set forth in f1).

XVI. Claims 51-53, drawn to a **method of treating a specific disease** using a specific composition comprising administering to the patient a composition comprising a **compound** that ***decreases*** **the level of expression** of a polypeptide as set forth in f1).

XVII. Claims 51-53, drawn to a **method of treating a specific** disease using a specific composition comprising administering to the patient a composition comprising a **compound** that ***increases*** **the activity** of a polypeptide as set forth in f1).

XVIII. Claims 51-53, drawn to a **method of treating a specific disease** using a specific composition comprising administering to the patient a composition comprising a **compound** that binds ***decreases*** **the activity** of a polypeptide as set forth in f1).

XIX. Claims 51-53, drawn to a method of treating a specific disease using a specific composition comprising administering to the patient a composition comprising a **compound** that is an **enzyme** that binds to a polypeptide according to any a1) to a15).

XX. Claims 51-53, drawn to a method of treating a specific disease using a specific composition comprising administering to the patient a composition comprising a **compound** that is a **receptor** that that binds to a polypeptide according to any a1) to a15).

XXI. Claims 54-55 and 57-62, drawn to a **method of diagnosing** a specific disease using a specific composition comprising **assessing the level of expression** of a specific natural gene encoding a specific polypeptide.

XXII. Claims 54-55 and 62, drawn to a **method of diagnosing** a specific disease using a specific composition comprising **assessing the activity** of a specific polypeptide.

XXIII. Claims 56 and 62, drawn to a **method of diagnosing** a specific disease using a specific composition comprising detecting **ligand-polypeptide complex** using antibody.

XXIV. Claims 65-66, drawn to a method of **identifying compound** that is effective in the treatment and/or diagnosis of a specific disease, comprising contacting **polypeptide** as set forth in a1) 1 to 15).

XXV. Claims 65-66, drawn to a method of **identifying compound** that is effective in the treatment and/or diagnosis of a specific disease, comprising contacting **polynucleotide** as set forth in b) 1 to 5).

XXVI. Claims 67-68, drawn to a method of **identifying compound** that is effective in the treatment and/or diagnosis of a specific disease, comprising contacting a transgenic animal that express higher level of a polypeptide.

XXVII. Claims 67-68, drawn to a method of **identifying compound** that is effective in the treatment and/or diagnosis of a specific disease, comprising contacting a knockout animal that express lower or absent levels of a polypeptide.

Linking claim 50 will be examined along with Groups XII through XXVII if any one of said Groups is elected.

Claim 50 links inventions XII-XXVII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim, claim 50. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The Groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I-XXVII lack unity of invention because the groups do not share same or corresponding technical feature.

Groups I-XXVII lack unity of invention because even though the inventions of these groups require the technical feature of protein that is a fragment that has greater than 50% sequence identity to an amino acid of SEQ ID NO: 10, this technical feature is not a special technical feature as it does not make a contribution over the prior art in view of WO 96/23866 (published August 8, 1996; PTO 1449).

Consistent with the international search report, the WO 96/23866 publication teaches a composition comprising saccular collagen of SEQ ID NO: 2 or fragment thereof with over 55% sequence identity to a fragment such as 120 amino acids of SEQ ID NO: 8, 55.9% over 111 amino acids of the claimed SEQ ID NO: 10 (see page 16, lines 9-11, claims 1-2 of reference, in particular). Further, the WO 96/23866 publication teaches various antibodies (page 7, claims 5-7 of reference), fusion proteins comprising the reference polypeptide, antisense nucleic acid that decreases the expression of the reference protein and their use in diagnosis and therapy and the making of transgenic animal (claims 19-20 of the reference, in particular).

Because Applicant's inventions do not contribute a special technical feature when viewed over the prior art, the inventions lack unity of invention.

Accordingly, Groups I-XXVII are not so linked as to form a single general inventive concept and restriction is proper.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

This application contains claims directed to the following patentably distinct species of (A) disease identifiable in claims 51, 62, 64, 66 and 68, (B) species of compound that is agonist identifiable claim 52, and (C) species of compound that is antagonist identifiable in claim 53, for example.

Should Applicant elected any one of Groups XII-XX, Applicants are further required to elect a species of (A) disease as set forth in identifiable in claims 51 and 64, and whether the polypeptide, nucleic acid, vector, ligand, compound or composition administered to the patient is an agonist or an antagonist as set forth in claims 52-53.

Should Applicant elected any one of Groups XXI-XXIII, Applicants are further required to elect a species of disease as set forth in identifiable in claim 62.

Should Applicant elected any one of Groups XXIV-XXVII, Applicants are further required to elect a species of disease as set forth in identifiable in claims 66 and 68.

The species of diseases are independent or distinct because these diseases differ with respect to their etiology, patient population and therapeutic endpoints and thus the disease lack the same special technical feature.

These species of agonist or antagonist compounds differ with respect to their structure and effect and thus the agonistic or antagonist compound lacks the same special technical feature.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in

scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh, Ph.D. whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Thursday from 9:00 a.m. to 6:30 p.m. and alternate Friday from 9: 00 a.m. to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The IFW official Fax number is (571) 273-8300.

Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong Huynh/
Primary Examiner, Art Unit 1644
January 29, 2010